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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,722	08/01/2005	Paul Townsend	D2018/20002	5121
3000	7590	12/10/2008	EXAMINER	
CAESAR, RIVISE, BERNSTEIN, COHEN & POKOTILOW, LTD. 11TH FLOOR, SEVEN PENN CENTER 1635 MARKET STREET PHILADELPHIA, PA 19103-2212				OSTRUP, CLINTON T
3771		ART UNIT		PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@crbcpc.com

Office Action Summary	Application No.	Applicant(s)
	10/537,722	TOWNSEND ET AL.
	Examiner	Art Unit
	CLINTON OSTRUP	3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 02 December 2005.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-13 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-13 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 07 June 2005 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/2/05</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

1. Claims 1-13 are pending in this application.

Priority

2. If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 119(e), a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim

filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11. Appropriate correction is required.

Drawings

3. The drawings are objected to because Figures 1 & 2 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP

§ 608.02(g). Evidence that figures 1 & 2 are prior art can be found in the specification on page 6, lines 8-11. Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. The drawings are also objected to because Figure 4, lacks a description of reference character "60" and Figure 5, shows a reference character "44C" and it appears it should be "44c". Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are

not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

5. The disclosure is objected to because of the following informalities: Page 1, line 16, appears to have an inadvertent period placed between the words "reduction" and "in".

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 1-10, 12 and 13 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Where a claim is directed to an apparatus attached to the human body or any part thereof the claim is directed to nonstatutory subject matter because the claim positively recites part of a human body.

See: 1077 Official Gazette, April 21, 1987.

Claims 1, 12 and 13 are rejected because they positively recite a user to define the apparatus. Claim 1 claims "a user wearing a facemask, for inhalation" in line 3; Claim 12 claims fluid for breathing is conveyed to a user upon inhalation" in line 3; and Claim 13 claims "fluid for breathing is conveyed to a user on inhalation" in line 2 and "a facemask, connected to a lung demand valve, and worn by the user" in lines 4-5. These rejections can be obviated by using the phrase "adapted to" or "configured to" prior to describing an apparatus being utilized by a user.

Any remaining claims are rejected as depending from a rejected base claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-2 and 5-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Mitchell (3,028,859)

Mitchell discloses a lung demand valve device (11) for use with breathing apparatus (Figure 3), for delivering breathable gas from a pressurized supply (10) to a user (via 14) for inhalation, the device (11) comprising a body (outer portion of 11) in which is housed a valve member (80), for controlling the rate of delivery of the breathable gas, a movable diaphragm (105) having a first face (110) exposed to pressure within the body and a second face (inside 140) exposed to pressure outside the body (via 145 when 146 is open), the diaphragm (105) being responsive to the differential in pressure between its first and second faces to control the valve member (80 via 100 &81), and a duct (140) arranged to direct exhaled air towards said second face of said diaphragm.

Regarding claim 2, the device disclosed by Mitchell is detachably mountable (via tubes) on a mask of a breathing apparatus.

Regarding claim 5, Mitchell discloses a duct portion (140) that is arranged (by forming a tubular member at its end) to abut an exhalation port of a mask.

Regarding claim 6, Mitchell discloses a duct (140) that is arranged to direct exhaled air (via 13) to a region (inside 140) surrounding the second face of the diaphragm (105), so as to flush ambient gases from said region (via 145 & 146).

Regarding claim 7, Mitchell discloses a device that comprises a cover member (130, 134 & 146) arranged to extend around the device and would inherently prevent the ingress of dirt into the housing, and wherein the duct (140) comprises a portion of said cover (130).

Regarding claim 8, Mitchell discloses a cover that comprises a plurality of portions (130, 134, & 146) which are detachably fixed together. See: figures 3 & 4.

Regarding claim 9, Mitchell discloses a device that comprises locating means (inlet & outlet of gases) arranged to co-operate with a mask (14) to inhibit rotation of the device (by symmetrical attachment to both sides) relative to a mask (14).

Regarding claim 10, Mitchell discloses a self-contained breathing apparatus (see: col. 1, line 64 - col. 2, line 30) including a lung demand valve device (11).

Regarding claim 11, Mitchell discloses a lung demand valve (11) suitable for use in a self contained breathing apparatus (col. 1, line 64 - col. 2, line 30), in which fluid (air) for breathing is conveyed to a user on inhalation, the lung demand valve (11) comprising: a first fluid path (110), a second fluid path (140), a flexible diaphragm (105), separating the first and second fluid paths, and wherein the second fluid path is open to the atmosphere (via 145 & 146).

Regarding claim 12, Mitchell discloses a cover (130, 134 & 146) suitable for use on a lung demand valve (11) for a self contained breathing apparatus (col. 1, line 64 -

col. 2, line 30), in which fluid (air) for breathing is conveyed to a user on inhalation, in which the lung demand valve (11) comprises: a first fluid path (110), and a diaphragm (105), enclosing at least a part of the first fluid path, wherein the cover (130, 134 & 146) provides the lung demand valve (11) with a second fluid path (140), so that the first and second fluid paths are separated by the diaphragm, and the second fluid path is open to the atmosphere (via 451 & 146), and wherein exhaled fluid is directed along the second fluid path to the diaphragm.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over applicant's admitted prior art and further in view of Brauer et al., (4,197,841).

Applicant's admitted prior art, as shown in figures 1 & 2, as evidenced by page 6, lines 8-11 of their specification, disclose a lung demand valve device (figure 1) for use with breathing apparatus (mask), for delivering breathable gas (gas) from a pressurized supply (13) to a user wearing a face mask (15), for inhalation, the device comprising a body (12) in which is housed a valve member (actuated by 24a) , for controlling the rate of delivery of the breathable gas, a movable diaphragm (26a) having a first face exposed to pressure within the body and a second face exposed to

pressure outside the body, the diaphragm being responsive to the differential in pressure between its first and second faces to control the valve member.

However, the admitted prior art lacks a duct arranged to direct exhaled air towards said second face of said diaphragm.

Brauer et al., discloses a respirator with a protective cover by placing a bag with air outlets isolated from the air inlets. As shown in figure 3, the bag (duct) has an exhalation valve (7) at the top which directs exhaled air to the exhalation holes (8a) while passing the gasses through the automatic lung (9). See: col. 3, lines 5-30 and figures 1-3.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have added a protective cover to the admitted prior art breathing device using the bag (duct) taught by Brauer in order to provide a self contained breathing device capable of functioning in extremely cold environments.

Regarding claim 2, Applicant's admitted prior art shows a device that is detachably mountable on a mask (at 18) of a breathing apparatus.

Regarding claim 3, once the admitted prior art device is attached to the mask, as shown in figure 1, it is permanently attached to the mask of a breathing apparatus.

Regarding claim 4, once the admitted prior art device is secured to the mask, as shown in figure 1, it is integral with a mask of a breathing apparatus.

Regarding claim 5, the duct portion (8 of Brauer) is arranged to abut the exhalation port (39 of admitted prior art in figure 2) of a mask.

Regarding claim 6, the duct (8 of Brauer) is arranged to direct exhaled air to a region surrounding the second face of the diaphragm, so as to flush ambient gases from said region (it will covers the automatic lung and the exhalation port from the mask).

Regarding claim 7,.the bag (8 of Brauer) is a cover member arranged to extend around the device and would preventing the ingress of dirt into the housing, and wherein the duct comprises a portion of said cover. See: figure 3 of Brauer.

Regarding claim 8, the cover (8 of Brauer) comprises a plurality of portions (8, 11 & 12) which portions are detachably fixed together.

Regarding claim 9, the cover comprises locating means (where 11 surrounds 13 of Brauer) arranged to co-operate with a mask to inhibit rotation of the device relative to a mask. See: figure 3.

Regarding claim 10, applicants admitted prior art (figures 1 & 2) discloses a self-contained breathing apparatus including a lung demand valve device.

Regarding claim 11, the applicants admitted prior art discloses a lung demand valve suitable for use in a self contained breathing apparatus (figure 1), in which fluid for breathing is conveyed to a user on inhalation (via 13), the lung demand valve comprising: a first fluid path (arrows up), a second fluid path (arrows down), a flexible diaphragm (26a) and Brauer teaches separating the first and second fluid paths, and wherein the second fluid path is open to the atmosphere (via 8a of Brauer).

Regarding claim 12, Brauer teaches a cover (8) suitable for use on a lung demand valve for a self contained breathing apparatus, in which fluid (air) for breathing is conveyed to a user on inhalation, in which the and applicants admitted prior art

discloses a lung demand valve that has a first fluid path (arrows up), and a diaphragm (26a) , enclosing at least a part of the first fluid path, and Brauer teaches the cover that would provide the lung demand valve with a second fluid path via 8a), so that the first and second fluid paths are separated by the diaphragm, and the second fluid path is open to the atmosphere (via 8a), and wherein exhaled fluid is directed along the second fluid path to the diaphragm (by virtue of it being covered).

Regarding claim 13, applicant's admitted prior art discloses a self-contained breathing apparatus in which fluid for breathing is conveyed to a user on inhalation, the apparatus comprises a face mask (10), connected to a lung demand valve (12), and worn by the user, a high pressure cylinder (13) containing the fluid (breathing gas) for breathing, a hose (14) for conveying fluid from the cylinder (13) to the lung demand valve (12), wherein the lung demand valve (12) comprises: a first fluid path (delivering gas) for conveying fluid for inhalation to the face mask (10), and a second fluid path is created by the bag (8) of Brauer for conveying exhaled fluid (air) from the face mask (10 of admitted prior art) to the atmosphere (via 8a of Brauer), and a flexible diaphragm (26a of admitted prior art), separating the first and second fluid paths, wherein exhaled air is directed to the diaphragm (via 8 of Brauer).

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: King (2005/0066966) teaches a breathing mask with an exhalation port used to rinse a membrane and is being provided to show the state of the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771

/Clinton Ostrup/
Examiner, Art Unit 3771